EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-02

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-D-12-050	08/02/2012 To 08/01/2014	WA 1-02 Air and Human Studies
	Base Option Period Number 1	

Contractor: WESTAT, INC.

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/05/2013 To 05/31/2014

Comments:
WA 1-02 Air and Human Studies: The Contractor shall perform the activities in the attached Statement of Work. The Contractor shall not duplicate any work previously performed or incur any cost previously incurred under any other Work Assignment performed under this or the previous Contract (EP-D-07-109).

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period	Cost/Fee	LOE
This Action:	08/02/2012 To 08/01/2014		235
Total:			235

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Edward Hudgens (Signature) (Date)		Branch/Mail Code: Phone Number: 919-966-0642 FAX Number:
Project Officer Name: Edward Hudgens (Signature) (Date)		Branch/Mail Code: Phone Number: 919-966-0642 FAX Number:
Other Agency Official Name (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Robin S. Harris Robin S. Harris (Signature)	11/5/13 (Date)	Branch/Mail Code: Phone Number: 919-541-0955 FAX Number:

1-02: Support for Air and Human Health Studies
WORK ASSIGNMENT STATEMENT OF WORK

I. Background and Objectives

This statement of work is designed to continue the efforts begun during previous Work Assignments on this (Contract EP-D-12-050, WA 0-01) and previous Epidemiology Support Contracts (Contracts EP-D-07-109 and 68-D-02-062). The Contractor shall not duplicate work performed for these earlier work assignments and shall utilize materials previously prepared as templates for future work. In particular, the contractor shall take full advantage of the Quality Assurance Project Plans, Data Management Plans, Database Documentation, Statistical Recommendations and Deliverables developed / submitted previously. In the case of the MICA Study, these database and data analysis methods and materials were developed during Work Assignments 0-02, 1-04, 3-02, and 4-02 (EP-D-07-109). MICA Study planning and sample collection efforts were completed during the previous EPA Contract under Work Assignments WA 3-03, WA 3-07, WA 3-11 and WA 4-02 with Westat, Inc.

The Environmental Public Health Division (EPHD) conducts clinical and epidemiological research to improve the understanding of human health risks associated with exposure air pollution and the development of Human Health Indicators which allow for hazard identification, risk characterization and the elucidation of environmental trends. Epidemiologic investigations study humans in less rigidly controlled, more natural settings by field studies or analysis of existing data. Biomarker methods for exposure, dose and susceptibility will be developed for and applied to a range of health effects including cancer, reproductive effects, cardiovascular disease, and respiratory effects. Laboratory analyses are used to improve assessments of exposure, biologically relevant doses, adverse biological or health effects, as well as to investigate mechanisms linking these phenomena. Studies are frequently designed and analyzed so as to characterize the similarities or differences between effects observed in humans and animals or in vitro systems; the data are then used by the Agency for risk assessment in the absence of human data. Investigations conducted by this division frequently involve collaborations within and outside the Agency, and emphasize interdisciplinary approaches that integrate complex data from existing records, questionnaires, clinical, and laboratory studies.

Database management, review of the results of previous statistical requests, statistical data analyses and review of the scientific literature are fundamental components for these activities. Additionally, a literature review is a significant component of any research paper submitted for publication in a peer-reviewed journal. Such a review may include studies from many scientific disciplines, including epidemiology, toxicology, ecology, exposure assessment, dosimetry, and atmospheric chemistry.

In addition to steps listed above, manuscript preparation requires the drafting of data tables and figures, and report or journal article sections including introduction, methods and materials, results, discussion, conclusions, acknowledgements, and literature cited. In most instances, specific formats and style guides must be used to allow for easy submission to scientific journals or the production of EPA Reports.

The EPA will provide materials such as data, outlines and rough drafts of manuscripts to be used as the basis for a literature review and final manuscript drafting.

The **Detroit Children's Health Study (DCHS)** is a case-cohort study for the assessment of the relationship between proximity to roadways and other sources of ambient pollutants and the prevalence of allergies and asthma among children aged 7 to 12 years. For DCHS, EPA attempted to recruit 700 children aged 7 to 12 years residing in the Detroit / Dearborn area whose parents completed the questionnaire distributed by Westat in WA 3-07 and agreed to be contacted for additional clinical examinations. An eligible child was any child with parental permission who was not an active smoker, and who had not had a respiratory infection within the last two weeks. The DCHS clinical examinations consisted of height, weight, spirometry, and exhaled breath measurements of these children. The other major components of DCHS included an exposure assessment and a questionnaire. An extensive background statement concerning the Detroit Children's Health Study was provided in WA 3-07 and in the Intramural Research Protocol for the Detroit Children's Health Study (1).

The **Mechanistic Indicators of Childhood Asthma (MICA) study**, a companion study funded through the EPA Computational Toxicology program, is a case-control study for the assessment of biological markers of exposure, early response, and susceptibility among children aged 9 to 12 years. For MICA, EPA recruited 205 children from a portion of the DCHS cohort who agreed to participate in the pulmonary measurements. The 205 children were selected so that approximately 100 children were expected to be moderate, persistent asthmatics and approximately 100 children had no prior history of asthma. The parents of these children were asked to collect house dust, indoor air, and outdoor air samples prior to the clinic visit and to provide additional questionnaire information on factors that could affect the analysis of their children's biological samples. At the clinic visit, each child was asked to provide samples of blood, urine, and fingernails; and measurements of blood pressure in addition to the DCHS clinical measurements mentioned above.

Previous Work:

In addition to the Work Assignments cited above, the EPA has secured institutional review approval of the MICA Study from the University of North Carolina's Committee on the Protection of the Rights of Human Subjects. The Contractor's Institutional Review Board, NHEERL's Associate Director for Health, and the EPA's Human Subjects Research Review Official have conducted their own reviews and have approved the study protocol.

Much of the database and statistical work required in this Work Assignment was begun during Work Assignments 0-02, 1-04, 3-02 and 4-02 (EP-D-07-109). While previous database and statistical support Work Assignments have required Global Information System (GIS) and spatial analysis work to be performed, the EPA does not anticipate the need for these types of work in this

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1 U.S. Environmental Protection Agency, Office of Research and Development, National Health and Environmental Effects Research Laboratory, Human Studies Division, Epidemiology and Biomarkers Branch. Detroit Children's Health Study: Intramural Research Protocol. Chapel Hill, NC. January 11, 2006.

Work Assignment.

The Environmental Public Health Division (EPHD) has several other Air and Human Health studies that may require technical editing, reference searches or the specific formatting of scientific articles or reports. One example is a study of the publicly available National Health and Nutrition Examination Survey data set(s) for associations between chemical body burden measurements within classes of chemicals, environmental, clinical and socioeconomic factors.

Objective: The current work assignment requires the Contractor to provide data analysis, statistical consultation, literature review and manuscript preparation support for Air and Human Health Indicators studies.

II. Task Descriptions

Task 1. Data Analyses, Statistical Consultation and Graphics Support: In previous WA's 0-02 on the current Contract; 4-02, 3-02 and 2-03 on the previous Epidemiology Support Contract; the Contractor, in consultation with the EPA, began the development of a method to assess the cumulative risk of multiple exposures, stressors and health indices. The EPA does not anticipate at this time any additional modeling using the cumulative risk score and multivariate models to further refine this method. The Contractor shall be prepared to update previously provided analysis results to support the conclusions presented in the draft papers, discussed below.

Using exploratory statistics reports delivered during the previous Work Assignments, the EPA identified several potential journal articles that required additional or amended tables and/or graphics prior to their submission. The Contractor shall provide graphics, tables and methodological descriptions of their statistical work that can be submitted to scientific journals with little or no editing by the EPA. The EPA anticipates that no more than 15 figures or tables, and no more than 3 statistical methods sections will be required during the Period of Performance of this Work Assignment. The Contractor shall be prepared to provide technical editing reviews of no more than 3 draft journal articles. The Contractor shall be prepared to format draft text, graphics and references according to the style guide(s) of journals as identified by the EPA. Since the draft manuscripts have been prepared by various collaborators using different statistical techniques, the Contractor shall be prepared to perform statistical analyses to confirm and verify the results presented in these draft journal articles, and identify sections with missing or incomplete information. If the Contractor identifies any missing or incomplete information in a draft, the Contractor shall be prepared to perform additional analyses to complete the draft journal article. The Contractor shall retain any new or modified programs or materials for submission to the EPA at the completion of the Work Assignment. The EPA may require the Contractor to provide the programming code developed to perform the tasks outlined above prior to the end of the Work Assignment for EPA review and QA activities. The Contractor shall be prepared to perform literature searches in support of conclusions drawn from the analysis work and be prepared to submit the results of the searches in EndNote libraries.

As part of the previous WA, the Contractor prepared an extract of NHANES data which will be used to support the Salivary Antibody Feasibility (SAFE) Study, a human health study. The goals of the SAFE Study are to validate the use of saliva assays to measure subclinical infections and to determine the prevalence of these infections in the general population. The Contractor shall incorporate the recently released NHANES toxoplasma gondii data for 2009-2010 into the previously delivered database using the same data documentation techniques and procedures. Whenever possible, the Contractor shall make use of the existing, publically available, NHANES data documentation. The ultimate goal of this documentation work is to create a clear, understandable and consistent set of database supporting documents that can be used by other collaborators and researchers with little or no instruction from the EPA.

The Contractor shall maintain liaison with the WACOR through conference calls, at an agreed upon interval, regarding the status of the activities within this Task. The Contractor shall prepare Agendas for the conference calls, distribute the Action Items and distribute Action Item updates during weeks without conference calls. Copies of all deliverables shall be sent to the WACOR, the COR and the CO (upon request).

III.Deliverables

Special reporting requirements include documentation of all sources and contacts so as to fully reference the sources of all information. The Contractor shall submit to the Work Assignment Contracting Officer's Representative (WACOR) the following deliverables:

Task 1. **Deliverable 1.** A detailed Work Plan, in response to the Task within this Work Assignment, shall be due 20 calendar days from the effective date of this Work Assignment for review by the Work Assignment Contracting Officer Representative (WACOR), Contracting Officer Representative (COR), and the Contracting Officer (CO). As part of this Work Plan, the Contractor shall also prepare a cost estimate for accomplishment of the Task within this Work Assignment. The Contractor shall also supply relevant information on the roles and responsibilities of any subcontractor. The content of the detailed Work Plan shall be in accordance with the terms of the contract and responsive to the requirements of this Work Assignment.

Task 1. **Deliverable 2.** The Contractor shall prepare monthly progress reports pursuant to the terms of the contract, monitor the budget and administer this Task through its completion. If additional Tasks are added to this Work Assignment, the Contractor shall coordinate their reports and administration duties across all of the Tasks within this Work Assignment.

Task 1. **Deliverable 3.** The Contractor shall prepare a final report summarizing all analyses, recommendations, reports, or comments provided for the Task during the Period of Performance of this Work Assignment. The final report shall provide documentation for any electronic data sets that may have been generated. Updated versions of any amended databases, data dictionaries, data sets, programs or documents, as well as all

graphics and tables generated during the Work Assignment, are due at the completion of the work assignment and in a format that has been approved by the WACOR. Copies of the Monthly Reports, conference call Agendas and the agreed upon Action Items shall be included as documentation of each Task's and the overall Work Assignment's course and progress. This report shall include suggestions for potential future work or improvements to the deliverables for any Task that has not been completed during the Period of Performance of this Work Assignment. A draft report is due 14 calendar days before the end of the Work Assignment. A final report, incorporating any EPA comments, is due at the end of the Work Assignment. Files submitted on CD or DVD shall have an accompanying Table of Contents in a format that has been approved by the WACOR.

Task 1. Deliverable 4. The Contractor shall provide results of automated analyses, manuscript reviews or updated manuscript materials no less than two weeks after receipt of the request. These deliverables shall be submitted electronically to the WACOR, the COR and the CO (upon request). All programming documentation is due at the end of this Work Assignment. The EPA may require the Contractor to provide the programming code used for specific data analysis or quality assurance tasks prior to the end of the Work Assignment for the EPA review and QA activities.

IV. Reporting Requirements

The Contractor shall furnish a copy of the Work Plan, as well as each section of the combined monthly technical and financial progress reports which relate to this Work Assignment directly to the Work Assignment Contracting Officer Representative at the same time progress reports are submitted to the Contracting Officer Representative and Contracting Officer. The work plan shall serve as the QAPP for this work assignment.

Special reporting requirements include documentation of all sources so as to fully reference the sources of all information. Deliverables shall be provided in hard copy and electronically on CD-ROM, DVD or via email. Reports shall be written in Word or PDF format, based upon approval from the WACOR. Three copies of the final report shall be provided to the WACOR and one copy to the COR and CO.

V. Work Assignment Contracting Officer's Representative Designation

The Work Assignment Contracting Officer's Representative will be:

Edward E. Hudgens
Chemist
US EPA/ORD/NHEERL/EPHD/EB (MD-58C)
Research Triangle Park, NC 27711
Telephone: 919-966-0642
Fax : 919-966-0655
Email: hudgens.edward@epa.gov

The preferred method of contact is by email.

VI. WORK ASSIGNMENT DURATION

The period of performance for this work assignment is from date of issuance through May 31, 2014.

VIII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

The contractor shall not engage in activities of an inherently governmental nature such as the following:

1. Formulation of Agency policy;
2. Selection of Agency priorities;
3. Development of Agency regulations.

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the COR or the Contract Officer.

The contractor shall also ensure that the work under each individual work assignment does not contain any real or apparent personal or organizational conflict of interest. The contractor shall certify that none exist at the time the work plan is submitted to the EPA.